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510(k) Premarket Notification Submission
AFrame Digital MobileCare Monitor

NOV 19 2012

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter:

510(k) Owner:	AFrame Digital, Inc.
Address:	1889 Preston White Drive, Suite 101 Reston, Virginia 20191
Contact Person:	Cindy Crump, CEO & President
Telephone:	571.308.0147
Date Prepared:	August 1, 2012

Device Information:

Trade Name:	MobileCare™ Monitor
Common Name:	MobileCare Monitor remote patient monitoring system
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency, 21 CFR 870.2910
Product Code:	DRG
Panel:	Cardiovascular

Substantial Equivalence:
Substantial Equivalence is claimed with respect to the following predicate device:

K103796 TeleMedCare Health Monitor

In addition, since the Class II functionality described in this PMN is being added to our previously cleared device, the AFrame Digital Inc. MyPHD™ MobileCare Monitor℠ (K090138) is referenced herein as supplemental information.

Device Description:
AFrame Digital's MobileCare Monitor is a communications platform consisting of a local wireless gateway, a remote computer server and software.

1. Local Wireless Gateway. A Powered Automated Network Data Aggregator (PANDA) is the wireless gateway to the remote server, similar to wireless routers used in homes and offices to provide wireless internet access. Three or more PANDAs are placed in a residential or patient environment to support internet- or cellular-based communications between the AFrame Digital MyPHD (personal health device) and a remote computer server. In some configurations the server will be in

the same facility. All wireless messages are securely encrypted with 256-bit AES. The PANDA access points form a reliable, low-power wireless network 'mesh' in the facility for complete wireless coverage of all residents with MyPHD watches. This functionality was cleared in the AFrame Digital MyPHD MobileCare Monitor submission (K090138) in April 2009.

2. Remote Computer and Software. The remote computer server communicates with the PANDA devices. It analyzes the messages received against alert thresholds established by designated staff or caregivers. Staff may make inquiries of the status of wearable monitors. The location of a wearable monitor may be determined from its position relative to nearby fixed-position PANDAs. The server will store messages and status information concerning the residents. Staff will be able to annotate records with support information related to individual residents and patients. To enhance caregiver productivity and mobility, alerts, resident location and other important person-specific information is available using a secure web browser application from a portable electronic device (PED), laptop or fixed-station PC. This functionality was also cleared in the AFrame Digital MyPHD MobileCare Monitor submission (K090138) in April 2009.

The remote computer server also communicates with COTS local wireless gateways that incorporate standardized wireless communications protocols such as Bluetooth to receive health-related data from commercially available, wireless measurement devices (e.g. blood pressure cuffs, pulse-oximeters, weight scales, blood glucose meters, etc.). AFrame Digital's configuration protocols and web-based software tools specify whether a measurement device may be used by a single user or multiple users. They also integrate data from these devices with other person-specific information without the transmission of personal health information. The server's software displays the data remotely to access-enabled users or caregivers over a secure browser, and provides tools for them to select patient-specific alert thresholds.

3. MyPHD™ Wearable Monitor. This is a small plastic housing and wrist strap with an external "panic" button. Some variations will have additional buttons that may be assigned a messaging or privacy function by the product software (soft-settable). Internally, there is an impact sensor that may indicate a fall and a skin temperature sensor to indicate if the monitor has been removed from the wrist. A microprocessor with an industry standard very low power wireless transceiver sends messages to a nearby PANDA. This functionality was cleared as a Class I Bed-Patient Monitor in the AFrame Digital MyPHD MobileCare Monitor submission (K090138) in April 2009.

Indications for Use:
The MobileCare Monitor□ remote monitoring system is intended as a support in the care of patients and the elderly in institutional, home, and community care settings. Intended users include the monitored individuals and their caregivers.

MobileCare Monitor includes a MyPHD™ personal help device that is intended to monitor patients and the elderly as they go about their daily activities. MyPHD can be affixed to the wrist, clipped to the waist or used in a bandage for attachment at other locations on the monitored individual, as determined by the patient or caregiver. MobileCare monitor provides the MyPHD location information, battery life and indication that it is being worn. MyPHD also includes a help button and a tri-axial accelerometer used to convey the degree of motion created by a wearer's movements to support an assessment of impacts.

MobileCare Monitor may also relay data from legally marketed Class I and Class II wireless medical devices to AFrame Digital secure remote server by means of industry standard networks and public carriers. These data are stored and may be retrieved with a secure web browser after the user presents satisfactory security credentials. Users may also request the data to be presented in graphical format.

Alerts can be sent when a patient presses a help button on the MyPHD or when any data value from MyPHD or relayed device exceeds an upper or lower limit threshold established by a user. These data include impact sensitivity settings and/or physiological measurements from relayed Class I and Class II devices. Rules may be created for reminders to take physiological measurements. Alerts are sent to the browser or to a computer or mobile device address that the user designates.

MobileCare Monitor is not interpretive or predictive, nor is it intended to provide an automated treatment decision or act as a substitute for professional healthcare judgment. All patient medical diagnosis and treatment are to be performed under the direct supervision and oversight of an appropriate healthcare professional.

Technological Characteristics:
The MobileCare Monitor is substantially equivalent to the predicate device in terms of the remote collection of health-related data, the wireless transmission of data from legally marketed, COTS medical devices (intended for home use), the transmission of data over wireless and internet networks to a remote server, the aggregation of data on a remote server, the display of data over security-enabled web browsers, the availability of software tools that allow designated caregivers to view and manage data and define alert thresholds based on available health-related parameters, and the ability to transmit alerts remotely to the portable electronic devices of designated caregivers.

Safety and Efficacy

A comparative analysis has established that MobileCare Monitor is substantially equivalent to the predicate device TeleMedCare Health Monitor. MobileCare Monitor – alone or authenticated to relay data from legally marketed wireless measurement devices – cannot itself cause injury to a user, does not control the delivery of treatment or therapy and is not marketed as a device used to render a diagnosis. In delivering services, MobileCare Monitor does not rely upon an assessment of clinical performance data. For these reasons, MobileCare Monitor raises no new questions concerning the safety and efficacy of the device.

Safety and efficacy are established through internal quality assurance testing to determine system reliability and data concurrence when integrated with third party measuring devices. In addition, MobileCare Monitor's configuration to accept data from legally marketed COTS wireless measuring devices was first evaluated in 2009 by independent clinical researchers in a Phase I grant awarded by the HHS National Institutes of Health (Grant number 1R43AG029196-01A1), who conducted a study made up of elderly participants on the usability of COTS wireless physiological measurement devices connected to MobileCare Monitor and degree of participant compliance with study protocols. The study protocol included completion by each study participant of a daily survey on a touchscreen device regarding their reactions to the telehealth devices. Data from these devices were automatically transmitted to the MobileCare Monitor, and evaluated by the researchers for usability and reliability. Usability was ascertained by examining the number of proximal and distal readings gathered by the measuring devices divided by the total number of expected readings and the number of readings received by MobileCare Monitor divided by the number of expected readings. Reliability was ascertained by examining system reliability and data concurrence. The researchers determined that an end-to-end configuration is a feasible solution to the problem of acquiring and recording both physiological and survey data from the elderly population.

Performance Testing

Also, MobileCare Monitor undergoes extensive component, end-to-end, integration and quality assurance testing as part of a comprehensive approach to the ongoing development and testing of the MobileCare Monitor system, as required by the Quality Standards Regulation. These include software requirements and specifications, potential hazard identification and remediation (Failure Modes and Effects Analysis – FMEA), a requirements traceability matrix, unit testing, release notes, QA/System testing, release management, a version management system, code and documentation control and a bug tracking system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 19 2012

AFrame Digital, Inc.
C/O Cindy A. Crump
1889 Preston White Drive, Suite 101
Reston, Virginia 20191

Re: K122333
Trade/Device Name: MobileCare Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: Class II
Product Code: DRG
Dated: October 31, 2012
Received: November 6, 2012

Dear Ms. Crump:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Attachment A

Indications for Use

510(k) Number (if known): K122333

Device Name: MobileCare Monitor

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MobileCare Monitor may also relay physiological data from legally marketed Class I and Class II wireless medical devices (e.g. blood pressure cuff, weight scale, blood glucometer, pulse-oximeter, etc.) to AFrame Digital secure remote servers by means of industry standard networks and public carriers. Physiological data transmitted from these devices are stored and may be retrieved with a secure web browser after the user presents satisfactory security credentials. Users may also request the data to be presented in graphical format.

Alerts can be sent when a patient presses a help button on the myPHD or when any data value from MyPHD or relayed device exceeds an upper or lower limit threshold established by a user. These data include impact sensitivity settings and/or physiological measurements from relayed Class I and Class II devices. Rules may be created for reminders to be scheduled for periodic physiological measurements. Alerts are sent to the browser or to a computer or mobile device address that the user designates.

MobileCare Monitor is not interpretive or predictive, nor is it intended to provide an automated treatment decision or act as a substitute for professional healthcare judgment. All patient medical diagnosis and treatment are to be performed under the direct supervision and oversight of an appropriate healthcare professional.

Prescription Use ___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _X_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122333